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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,212	07/13/2001	Venkatraman Ramakrishnan	256602000600	3863

25226 7590 05/27/2003

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EXAMINER
LY, CHEYNE D

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 05/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/905,212	RAMAKRISHNAN ET AL.	
	Examiner	Art Unit	
	Cheyne D Ly	1631	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *March 31, 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *5-11 and 14-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,12 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5, 9,10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election with traversal of Group I, claims 1-13, in Paper No. 14, filed March 31, 2003, is acknowledged.

2. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 5-11 have been withdrawn due to being directed to species other than the elected species, an antibiotic which is a paromomycin.

4. The requirement is still deemed proper and is therefore made FINAL.

5. Claims 1-4, 12, and 13 are examined on the merits.

PRIORITY

Acknowledgment is made of applicant's claim for foreign priority based on applications filed in the United Kingdom. It is noted, however, that the certified foreign priority documents are not in the instant application. Therefore, the priority cannot be granted without certified copies, and, certified translations if the documents are in a foreign language. It is suggested that Applicants resubmit priorities documents for consideration.

OBJECTIONS

6. The title of the invention is not descriptive. The title is objected to because the title is directed to a crystal structure of the 30s ribosome and its use, however, the claims are directed to only the crystal structure of the 30s ribosome. A new title is required that is clearly indicative of the invention to which the claims are directed. This suggested new title is "Crystal structure of the 30s ribosome."

Claim Rejections - 35 USC § 112, Second Paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Specific to claim 1, table of antibiotics Z, the table has species beyond the elected specie, paromomycin, which causes the claim to be vague and indefinite. Streptomycin, spectinomycin, tetracycline, pactamycin, and hygromycin B are non-elected species; therefore, it is unclear to which specie the claimed invention is directed. Further, it is unclear what is controlling the metes and bounds of the claimed invention. Clarification of the metes and bounds is required.

10. Specific to claim 12, line 3, the phrase "better (numerically less)" causes the claim to be vague and indefinite. It is unclear whether the 30S ribosomal subunit is determined to be better or numerically less. The limitation "better" is unclear in that it is unclear as to what the subunit is better for, for example, a numerically less resolution may be worse regarding the difficulty in time and effort to obtain. Clarification of the metes and bounds is required.

LACK OF ENABLEMENT UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-4, 12, and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a crystal structure of the *Thermus thermophilus* 30 S subunit having a resolution of 3.05 A, which have atom coordinates instantly disclosed, does not reasonably provide enablement for any 30 S subunit or any 30 S subunit having a resolution numerically less than about 3 A (See ¶ 10 of this instant action). Further, claims 1-4 and 13 contain the open claim language word "having" in line 1 of each claim, thus, including crystals, which contain more structure than the unit cell dimensions as defined in Tables 1-4. Therefore, the specification is not enabled for those crystals beyond those, which consist of a structure as defined by the co-ordinates of Tables 1-4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

12. Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

13. It is acknowledged that the applicant has disclosed information to enable one skilled in the art to make the crystal of the Thermus thermophilus 30 S subunit having a resolution of 3.05 A (Page 24, lines 28-30). However, it is well documented that protein crystallization is in essence a trial-and-error method, and the results are usually unpredictable (Drenth, J.). Further, as recently as November 1, 2002, Science published a New Focus article depicting the current state of the art for protein crystallization that supports the unpredictability of the art. In essences, protein crystallization is still a trial and error process because the current technology for producing protein for the crystallization process is unpredictable, which results in high failure rate for proteins that are being crystallized. Therefore, researchers continue to have trouble generating sufficient protein required for the crystallization process (New Focus, Science, 2002). In light of the difficulty of the protein crystallization process, it is, therefore, unreasonable to expect one skilled in the art to make any 30 S subunit crystal structure, any 30 S subunit crystal structure having a resolution numerically less than about 3 A or crystals beyond those, which consist of a structure as defined by the co-ordinates of Tables 1-4, without undue experimentation.

LACK OF WRITTEN DESCRIPTION 35 U.S.C. § 112, FIRST PARAGRAPH

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

16. It is acknowledged that Applicants disclose the crystal structure of the *Thermus thermopilus* 30S subunit having a resolution of 3.05 A (Pages 24, lines 28-30). However, Applicants do not provide disclosure for any 30S subunit having a resolution less than 3 A.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

17. Claim 12 is rejected under 35 U.S.C. 102(b) as being clearly anticipated Clemons et al. (1999).

18. Clemons et al. discloses the crystal structure of a bacterial 30S ribosomal subunit at 5.5 A resolution is better than about 3 A (Abstract). Consistent with the limitation of "better" in claim 3, the crystals of Clemons are improvements over those reported earlier because the double-helica...and B-sheets of proteins can be identified (Page 833, column 2, lines 12-17 and page 836, column 1, lines 1-2). (See ¶ 10 of this instant action)

DOUBLE PATENTING

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

20. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

21. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

22. Claims 1-4, 12, and 13 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 09/904,779 in view of Ramakrishnan et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application and the copending application claim a crystal of a 30S subunit with identical unit cell dimensions. It is acknowledged that the copending application does not claim a crystal of a 30S subunit bound to a paromomycin antibiotic as in the instant application. However, the copending application discloses, "the 30S provided by Table 1 may be used to examine and determine the binding of antibiotics such as paromomycin" (page 11, lines 23-25). One of ordinary skill in the art would have been motivated to examine the specification for the types antibiotics that bind to the 30S subunit as disclosed in the copending application. "The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. Further, those portions of the

specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent." (MPEP § 804 (II) (B) (1)) Therefore, it would have been obvious to make of crystal of a 30S subunit bound to paromomycin of the instant application.

23. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

CONCLUSION

24. NO CLAIM IS ALLOWED.

25. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 193), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

28. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
5/21/03

ARDIN H. MARSCHEL
PRIMARY EXAMINER